

REMARKS

The Examiner objected to the Abstract as being inconsistent with the first sentence of the published Abstract of PCT/FR97/00334. In response, the Examiner is asked to reconsider and accept the Abstract submitted with the June 21, 2000, Amendment for use in the present case. The submitted Abstract is substantially the same as the Abstract published with the PCT application, and has only been amended to put it in better form relative to United States Patent Office procedures. (In this regard, it is understood to be a common practice for the USPTO to object to the use of "is disclosed" in an Abstract.)

In the Action, claims 9-16, which are all of the claims remaining in the case, were rejected under 35 U.S.C. §112, first and second paragraphs. The claims were rejected under the first paragraph of §112 as containing subject matter not described in the specification in such a way to enable one skilled in the art to make or use the invention. The claims were rejected under the second paragraph of §112 as being indefinite for numerous reasons.

In response, claim 9, the only independent claim in the case, together with claims 13, 14, 15, and 16 have been amended. These amendments have been made in order to overcome all of the Examiner's rejections and objections to the subject matter of claims 9-16 as originally presented. It is now believed that these amendments put all of the claims in proper form for allowance.

In claim 9, the claim has been retyped and resubmitted in its proper form in order to make clear that there is only one ribonucleic arm and that the functional arm in part (a)

is the functional amino acid arm. The *Campylobacter* bacteria species has also been deleted from claim 9 as being redundant with the *Helicobacter* species. It is believed that these changes to claim 9 overcome all of the §112 rejections to the subject matter of the claim as originally presented.

In the dependent claims, claims 10, 11, and 12 were not amended in any manner since there do not appear to be any specific objections to them in the Action. Dependent claims 13, 14, 15, and 16, however, have been amended in various ways in order to overcome the specific objections to them as recited in the Official Action. For example, the "anti-bacterial antibodies" of claim 13 has been amended to point out that the antibodies are specifically "anti-*Helicobacter* sp. antibodies" and that the recitation "avoidance . . . are avoided" has been deleted and more appropriate language substituted for it.

In claim 14, the "antibiotic-resistant bacteria" has been further defined to be the antibiotic-resistant *Helicobacter* sp. as more specifically pointed out in the specification.

Dependent claim 15 has been amended in numerous ways in order to respond to the Examiner's objections and comments. For example, the term "the formulation" in line 2 has been modified to indicate that the complex is formulated to enable the simultaneous administration thereof. The expression "major anti-inflammatory agents of the corticoid type" has been amended to merely refer to "corticosteroids." Those terms have the same

definition, as shown by the attached copy of the Dorland Medical Dictionary. Indeed, the terms "corticoid" and "corticosteroids" have the same definition.

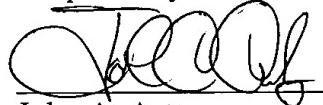
The Examiner's comments relative to the remaining portions of claim 15 have been rendered moot by the cancellation of that portion of the claim. In this regard, the Examiner is correct that "bacteriolytic" is redundant with "bactericidal" since in both cases the use of such products leads to the death of the bacteria. In that way, bacteriolytic is redundant and thus has been removed from the claim.

In claim 16, the objection due to lack of antecedent basis for "said formulation" has been overcome with language similar to the language of amended claim 15.

As to the Examiner's comments objecting to the "routes" as being vague and confusing, the group has been revised to put it in better form.

In view of the foregoing, it is submitted that all of the claims remaining in the case, namely claims 9-16 as amended, are in proper form and patentably distinguish from the prior art. Accordingly, allowance of the claims and passage of the application to issuance is respectfully solicited.

Respectfully submitted,



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"VERSION WITH MARKINGS TO SHOW CHANGES MADE"

Claims 9 and 13-16 have been amended as follows:

9. (Amended) An immunomodulatory and anti-*Helicobacter*-specific vaccine complex comprising:

- (a) dual molecules constituted by covalent coupling of a functional amino acid arm, ensuring binding to a target, with a genetic ribonucleic acid arm corresponding to the coded description of the composition of [the] said functional amino acid arm; and
- (b) bacterial membrane fractions containing glycopeptides and/or lipopolysaccharides,

[the] said ribonucleic acid arm being of ribosomal origin being extracted from bacteria selected from the group consisting of *Helicobacter pylori*, *Helicobacter hepaticus*, *Helicobacter coronari*, [*Campylobacter*, and] or mixtures thereof.

13. (Amended) The immunomodulatory and vaccine complex according to one of claims 9-11 for use as an anti-idiotype vaccine against the idiotype of [anti-bacterial antibodies wherein avoidance of recidivations of the initial digestive tract pathology are avoided] anti-*Helicobacter* sp. antibodies which make it possible to avoid recidivations of the initial digestive tract pathology caused by *Helicobacter* sp.

14. (Amended) The immunomodulatory and vaccine complex according to one of claims 9-11 for use against antibiotic-resistant *Helicobacter sp.* bacteria which are resistant to conventional treatments.

15. (Amended) The immunomodulatory and vaccine complex according to one of claims 9-11 wherein [the formulation of the] said complex [enables] is formulated to enable the simultaneous administration of [the] said complex together with substances selected from the group consisting of [major anti-inflammatory agents of the corticoid type,] corticosteroids, antibiotics, antisecretory agents such as proton pump inhibitors, products with bacteriostatic effect, and products with bactericidal effect [and products with bacteriolytic effect, for eradicating *Helicobacter* generating pathogeneses by factors linked to the bacterium such as various cytotoxins and inflammation mediators like Interleukin I and tumor necrosis factor alpha, or by factors linked to the host].

16. (Amended) The immunomodulatory and vaccine complex according to claim 15 wherein said [formulation enables] complex is formulated to enable the administration of said complex by a route selected from the group consisting of [infusions, intravenous injections, transdermal devices] intravenous route, transdermal route and per os.